Ethical Research Practice with Human Participants: Problems, Procedures, and Beliefs of Funded Researchers

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Although Federal and local guidelines provide general advice as to inform researchers regarding ethical practice (1 - 3), little information is available regarding how researchers carry out such ethical procedures. Despite the use of Institutional Review Boards (IRBs) to monitor ethical practice, there is great variability in how these boards operate and what types of policies are deemed acceptable (4). Similarly, it appears that psychopathology researchers greatly differ in their practices on how to assess and handle participant distress or injury (5 - 7). In some specialty areas, such as depression, there is preliminary evidence that most researchers routinely give referrals (8). Nevertheless, the range of practice is not known.

The need to document how different biomedical researchers implement ethical research policies is important in order to generate and develop viable and informed research policy. For example, it is helpful to understand how researchers recruit participants, train staff, obtain informed consent, and debrief participants (9). Furthermore, specific policies about response and compensation with regard to responding to participants' distress, worsening of conditions, confidentiality issues, informed consent, and other ethical dilemmas across different groups of human research participants is also needed. Sharing such information among researchers from different disciplines, who use different methodologies and research samples, can help to identify the range of options and the need for training initiatives. Finally as technology makes research more global, local community standards of practice may no longer be adequate to understand good research practice (10). To compound this issue, distinctions between research and clinical work and research and organizational consulting are blurring with the trends in program evaluation. Finally, advances in science have made human experimentation itself more complex. Hence there is a need to share information and understand the range of ethical practice in the field so we are better able to respond to these challenges and equipped to create policy in the future.

Currently it is unknown how often research-related injuries and problems occur in the course of routine research protocols. Although flagrant violations are reported or receive media attention, there has been no attempt to quantify the prevalence of such problems in routine practice (11). In order to understand participants' responses it is also important to ascertain the actual prevalence rates of research-related costs and injury across a wide range of samples to determine what groups need

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additional safeguards. These risks must be quantified to include both minor costs (abrasions, emotional distress) and major costs (death, disability, and needed hospitalization). Identification of the subgroups at greatest risk for research related harm could help inform policy (12).

Finally the expertise of researchers and opinions need to be shared. As documented, opinions and assumptions about possible risks and benefits of research participation shape ethical appraisals of research (13 - 17). Documenting experienced scientists' opinions and attitudes toward IRBs and research risk, can help establish a clearer understanding of the values that may shape research and research policy.

The goal of the current study is to delineate the rates and types of potential research-related injuries as well as the range of ethical practices and beliefs. This is important since several studies document the range of ethical research practice, but none of them actually assess the prevalence and types of risks (8).

First, it was hypothesized that there is considerable variability of research policies and procedures both within and across types of research and sample characteristics with those researchers working with psychiatric illness being more protective than researchers in other areas. Policies and procedures were defined as (a) level informed consent policy, (b) emergency policies, (c) determination of research- related risk, (d) debriefing procedures, (e) use of referrals, and (f) follow-up procedures.

Second, it was hypothesized that the research risks experienced by psychiatric health groups will be significantly greater than those experienced by the medical physical health group. In addition, it was hypothesized that researchers who studied psychiatric and medical samples were expected to report significantly greater rate of research risks than the non-psychiatric or medical samples. Research risk was defined as (a) Incidence of confidentiality violations for suicide, homicide, and abuse status; (b) Incidence of participants' condition worsening; and (c) Incidence of complaints and or suits filed against researcher or institution.

Method

We generated a list of 3,684 investigators who received federal funding for research projects pertaining to four at-risk groups. Specifically, researchers who studied humans with schizophrenia (n = 264), cardiovascular disease (n = 1472), major affective disorder (n = 899), and traumatic stress (n = 564) were identified from relevant NIH institutes using the Community of Science National Institute of Health database of funded grants (http://cos.gdb.org/best/fedfund/nih-select/inst.list.html) and the Veterans Administration Medical Center grant database (http://www.va.gov/research/research.html). These groups were chosen to represent medically and psychiatric samples that are hypothesized to be at greater risk for research-related injuries. In addition, we identified a pool of 485 federally funded investigators who study cognition in non-patient samples to represent a group hypothesized to be a relatively lower risk for research-related research.

Relevant grant proposals were identified by conducting a search of all proposals that had titles which contained a relevant key word. For example for studies on depression, depression needed to be in the title. For traumatic stress studies, PTSD, trauma or stress needed to be in the title. A detailed listing of key words and the systematic manner in which certain protocols were eliminated is available from the first author. Studies that crossed topic domains, used minors, used animals, or were post-mortum human studies were eliminated from the pool of studies. All treatment studies were eliminated, since they have unique risks and benefits that were not assessed in this study. All projects that were funded as multi-site collaborative studies were also eliminated since it was assumed the ethical considerations might vary across site. Ultimately, 69 funded researchers who study cognition, 79 who study schizophrenia, 61 who study lung-cardiovascular disease, 56 who study affective disorders, and 49 who study violence/PTSD were contacted.

A cover letter, 7 page survey form[1], and return envelope were sent to 314 researchers. A reminder card was sent one month later to all responders and non-responders. The survey began with general information about the respondent's demographics, and research and clinical experience. The researcher was asked to complete the questionnaire in regard to the most recent funded grant. Questions pertained to the setting, sample, type of research, number of sessions, participant characteristics, staff/training and supervision. Then questions about informed

consent, confidentiality issues encountered, participants' reactions, emergency policies, and injuries were attached.

Results

A total of 101 surveys were returned yielding a 32% response rate. Eleven surveys were dropped from the analysis because they were post-mortem studies (n = 4), used minors exclusively (n = 1), focused on substance abuse, HIV, or personality disorders (n = 4), animal studies (n = 1) or couldn't be classified into the groups based on the responses (n = 1). Of the 9 researchers who participated, 52.2% studied mental health (PTSD n = 12, schizophrenia n = 16, major affective disorders = 19), 24.4% studied cardiac or health problems and 23.3% studied "normal" cognition.

Participants

The 90 principal investigators were comprised of primarily Ph.D. trained researchers (73%) and M.D.s (19%). There were more males (63%) than females (37%) represented, and the majority of respondents were Caucasian (94%). The respondents' experience with research ranged from 2 to 49 years and had received a mean of 2.8 (SD = 1.8) federally funded grants in the 5 years prior to the study. The group of researchers reported a mean of 70 peer-reviewed publications, a median of 44 and a mode of 150. Only 20% reported completing a course in research ethics during advanced training. Despite this lack of formal training, 73% felt that they kept current with ethical issues and 50% felt they kept current with legal issues in research. Only 6% and 22% felt they were not current regarding ethical and legal research issues, respectively.

Research Procedures

Informed Consent Policy. With respect to informed consent, the majority of the sample (97%) provided written informed consent and 48% endorsed using methods to assess participants' comprehension of the consent form. Of the 39 respondents who provided open ended descriptions of these methods, 25 asked participants if they had questions, 3 had the interviewer certify person heard and understood, 3 used independent monitors, 2 relied on other indicators (fluency, literacy, neurological status), 1 used family consent, 1 used structured consent, 2 asked the respondent to repeat questions, and 2 relied on signature to indicate comprehension. Although 85% reported no need to investigate if the identified participant could legally provide consent, the remaining 15% reported a need ranging from once (7%) to eighty-five times (1%).

With respect to informed consent, 53% of these researchers indicated that there were instances in which the confidentiality of the research participant might be broken. As predicted, this policy differed by type of sample group [x^2 (2, n = 85) = 10.75 p =<.05], with 66% of those who worked with mental health groups, 55% of those who worked with physical health groups, and 21% of those who studied cognition stating instances in which the research team would consider breaking the confidentiality of the research record. Among the group who informed participants about confidentiality issues, 55% reported communicating this in specific rather than general terms.

Emergency Policy. Seventy-eight percent (n = 61) of the researchers endorsed having a protocol in place a priori to respond to emergencies. The groups significantly differed in this policy [x^2(2, n =78) =32.15, p <.05] such that 95% of mental health researchers, 90% of physical health researchers, and 28% of cognitive researchers reported such emergency policies in place. Among the 47 who provided open ended descriptions of these policies, 15 described use of emergency on-call personnel, 8 cited they had "written policies," 6 used standard local protocols, 6 cited immediately contacting the project director or principal investigator, 5 trained staff in Cardio Pulmonary Resuscita tion (CPR), and 3 discussed continuous monitoring during research. The remaining four described emergency medication, medical response plan in lab and for evacuation, methods for handling high blood pressure, and one general training how to respond to a variety of situations.

Determination of Research-Related Risk. Seventy-eight percent (n = 62) of the researchers sampled reported keeping records regarding the "frequency to which individuals experienced negative and noticeable reactions." Mental health researchers reported significant greater documentation than health or cognitive researchers [x^2 (2, n = 81) = 19.79, p < .05] such that 88% of mental health researchers, 79% of physical health researchers, and 52% of cognitive researchers kept such records.

Debriefing Procedures. Sixty-four percent (n = 57) of the researchers conducted debriefings

	Ranking			
Factors	Least important	Important	Fairly Important	Most Important
Manipulation check	24 (63%)	5 (13%)	8 (21%)	1 (3%)
Educate participants	1 (2%)	18 (33%)	7 (13%)	28 (52%)
Check on participant	7 (14%)	12 (24%)	10 (20%)	21 (42%)
Express gratitude	6 (11%)	9 (16%)	26 (46%)	15 (27%)

Table 1. Number (and percentage) of participants ranking relative importance of 4 factors in planning debriefing.

after the research protocol. In fact, 70% of mental health professionals, 42% of health researchers, and 71% of cognitive researchers used such debriefings [x^2 (2, n = 80) = 5.06, p =.08]. The majority (80%) of these debriefings were conducted orally, although 6% were conducted in writing, with 14% conducted in both formats; there was no statistically significant difference among the groups regarding format [x^2 (4, n = 51) = 4.48, p = .34]. The majority of these debriefings were done in individual sessions (88%) rather than group (4%), varied (6%) or family formats (2%); this did not vary significantly among groups format [x^2 (6, n = 51) = 9.05, p = .17]. As can be seen on Table 1, investigators felt debriefings were most important for educating participants and checking on participants. It is interesting to note that manipulation checks were deemed least important.

Use of Referrals. Forty-one researchers (46% of the sample) responded to the item about referral policy. Among those who responded, 20% reported providing referrals to all participants, 12% to those participants who indicated interest, 17% to only those in distress, 42% to those either interested or distressed, and 10% in "other" circumstances. Three researchers described such other circumstances as "offered to all deemed appropriate, but given to those interested;" "two found to have physical disorders," and "all those screened with high blood pressure."

Given this practice, the number of referrals for non-emergencies ranged from 0 to 90 (mean = 4.76, s.d. =13.02; mode =0). The mean number of referrals for the mental health, health and cognitive research teams were 8.56 (S.D. = 17.83), 2.29 (S. D. = 4.10) and .40 (S.D. =1.05) respectively, but these differences did not meet criteria for statistical significance [F (2, 65) = 2.9, p = .062].

With respect to actual practice regarding referral for immediate hospitalization, 6 researchers recommended immediate referral for a condition or concern, (with two researchers recommending it once, and the rest experiencing it twice, three times, four times and 10 times). It is unknown if these referrals were based on research-related injuries, or other conditions uncovered during the protocol.

Follow-up procedures. Fifty-four percent (n = 41) of the researchers reported follow-up efforts to determine if participants experienced a worsening of condition. These efforts significantly differed across groups [x^2 (2, n = 76) = 14.35, p <.01] such that 67% of mental health researchers, 55% of health researchers, and 8% of cognitive researchers used such methods. In terms of actual numbers, 24 researchers reported conducting a follow-up at least once to check on a participant.

	Never	**Infrequently**	**Sometimes**	**Regularly**	**Always**
Suicidality	58 (64%)	20 (24%)	4 (4%)	2 (2%)	1 (1%)
Homicide	76 (91%)	5 (6%)	2 (2%)		1 (1%)
Child abuse	72 (85%)	9 (11%)	2 (2%)		2 (2%)
Elder abuse	78 (94%)	4 (5%)			1 (1%)
Abuse of the disabled	78 (94%)	4 (5%)			1 (1%)
HIV status	64 (77%)	9 (11%)	8 (10%)	2 (2%)	
Substance abuse	49 (59%)	10 (12%)	14 (17%)	9 (11%)	1 (1%)
Criminality	68 (83%)	9 (11%)	1(1%)	3 (4%)	1 (1%)
Violence toward partner	67 (80%)	11 (13%)	2 (2%)	3 (4%)	1 (1%)
Other	50 (94%)	3 (6%)			

Table 2. Number and (Percentage) of researchers who faced confidentiality issues.

Research Risks

Incidence of confidentiality violations. The research staff occasionally faced confidentiality dilemmas as shown in Table 2, with substance abuse being the most frequently encountered issue. However, only 8 researchers actually broke confidentiality. Of these 8, 6 studied mental health (n = 3 mood disorders, n = 2 schizophrenia, n =1 PTSD), 1 studied normal cognition, and 1 studied health conditions. Among those researchers who described the specific circumstances, two reported needing to hospitalize at least one participant against his/her will, three reported having to file at least one report to the authorities, and two reported needing to warn at least one person in danger.

Incidence of participants condition worsening. During the protocol a range of emotional and physical experiences were encountered (See Table 3); clearly crying appeared most often. Although it was rare that a participant became medically compromised, it did occur. Twelve researchers (13%) reported at least one research-related injury. Two researchers reported that at least one participant had a research-related infection. Five researchers reported at least one case of temporary disability, and none reported research-related death. It should be noted that only 53% of researchers reported knowing how many participants experienced an immediate worsening of condition (research related injuries) after completing the research protocol; Knowledge of research-related injuries was not related to type of research conducted [x^2 (2, n = 73) = .42, p = .81]

Incidence of complaints filed against a researcher or institution. In this sample, 18% reported infrequent complaints about research staff's conduct. Two percent (n =2) reported complaints filed against the institution however none resulted in legal proceedings. On the other hand, 77% of researchers reported that participants thanked them, with 33% reporting this occurring sometimes, and 12% reporting this as a regular occurrence.

Discussion

In this preliminary study, 90 federally funded researchers who work with human participants responded to a survey about ethical research practice. There seems to be a great variation in ethical practice among distinguished researchers, although all these research participants were sensitive to research-related ethical dilemmas.

Policies

There is a great deal of variation in research policy implementation. Although nearly all use written informed consent, researchers varied in the detail that they provide participants about the limits of confidentiality. Although the majority of researchers developed emergency policies and debriefing procedures, the nature of these procedures also varied. Although often required, 32% did not keep records of participants' negative and noticeable reactions. Approximately half the researchers reported

	Never	Infrequenty	Sometimes	Regularly	Always
Cried	35 (42%)	24 (29%)	16 (19%)	7 (8%)	1 (1%)
Became hostile or angry	33 (43%)	35 (42%)	13 (16%)	3 (2%)	0
Experienced Panic Attacks	59 (71%)	17 (21%)	6 (7%)	1 (1%)	0
Expressed extreme fear	55 (66%)	16 (20%)	8 (9%)	4 (5%)	0
Reported feeling spacey	51 (62%)	18 (22%)	12 (15%)	1 (1%)	0
Became medically compromised	66 (81%)	14 (17%)	2 (2%)	0	0
Threatened the research staff	71 (87%)	10 (12%)	1 (1%)	0	0
Other	33 (86%)	2 (5%)	1 (3%)	1 (3%)	1 (3%)

Table 3. Number and percentage of researchers who encountered participants' emotional or physical response to research.

using follow-up methods to check on participants' condition. However, less than half the sample responded to the item regarding the use of referrals and those that did respond indicated a range of practices with respect to referring to other agencies. As anticipated, researchers working with psychiatric illness being more protective and explicit about policies for emergencies, risk documentation, and follow-up procedures but not for debriefing.

Risks

With respect to research risk, a minority of researchers reported having to deal with confidentiality issues, worsening of conditions, and complaints from participants. However, emotional and physical symptoms were encountered. In particular, 58% (n = 48) experienced crying, and 12 researchers (13%) reported temporary research-related injuries. Given that several of these studies were about health conditions, it is difficult to evaluate if these reactions were elicited by research participation, or were symptoms that individuals experienced irrespective of research participation. These reactions need to be examined in future studies in the context of baseline functioning of individuals to further understand if they meet the requirements of minimal risk. Nonetheless, the data are consistent with claims that the physical hazards of being a research participant are minimal even among medical procedures (18). Although, these risks appear minimal, they might be an underestimate given that about half the researchers did not document or know the number of participants whose condition worsened.

Finally, very few researchers received formal training in research ethics although the majority were confident that they were up to date in ethics, and half felt prepared for legal challenges. Given that researchers thought highly of their respective IRBs, continuing education may be best implemented through local IRBs.

There are several limitations to this study. First sample bias and demand characteristics may have affected the generalizability of these results. Although the extensive comments written on those returned surveys suggest that researchers were interested in sharing their experiences, sample bias may have affected the results. Second, while this study reveals a diversity of ethical practices, the quality of ethical implementation is not examined. Hence it is not known if this diversity suggests unsuccessful or successful flexibility of methods in responding to the needs of human participants.

Although the participation rate precludes generalizing to all researchers, these preliminary results provide information that can be useful in designing training and compliance policy. In particular, the diversity of responses suggests the need for cross-training across subspecialties to share perspectives. Individuals with risk factors may not only present for studies of health and mental health problems, so it can be helpful to share approaches across specialties. For example, although the majority of research-injuries were identified among those mental heath studies, they were not exclusively there. Furthermore it is unclear, given the lack of documentation and investigation, if this reflects better preparedness of mental heath researchers or greater risk in these studies. Future studies may be able to better examine this by ongoing quality control (19).

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Notes

1. A copy of the survey is available from the first author.

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